UNITED STATES DISTRICT COURT EASTERN DISTRICT OF WISCONSIN MILWAUKEE DIVISION

UNITED STATES OF AMERICA, ex. rel. JONATHAN B. FERING

PLAINTIFF/RELATOR

| v. | Civil Action No. | |
|-------------------------|------------------|-------------------|
| CENTER FOR PAIN MANAGEM | MENT, S.C. and | |
| NOSHEEN HASAN, M.D. | | DEFENDANTS |

Filed Under Seal

COMPLAINT

Jury Trial Demanded

This is a Complaint brought on behalf of the United States of America, by Jonathan B. ("Jon") Fering as Relator/Plaintiff, for treble monetary damages, civil penalties, and related further relief, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. §§ 3729 - 3720 ("FCA"), against each entity and person named as Defendants above.

The Parties

1. Plaintiff/Relator Jonathan B. ("Jon") Fering, an adult citizen of the United States, is a resident of Chaska, Minnesota. Relator Fering for approximately thirteen years has served in Minnesota, Wisconsin, and other Midwestern states as a Director of Sales, a Territory Sales Manager, and otherwise as a marketer of hospital and physician

office laboratory equipment and systems. All of the information set forth below was gained by Relator Fering in that capacity, and through non-public sources of information.

- 2. Defendant Center for Pain Management, S. C. (hereafter, "Defendant Clinic"), is a medical clinic now located at 6200 West Center Street in Milwaukee, Wisconsin.
- 3. Defendant Nosheen Hasan, M.D., is a practicing physician in the Milwaukee, Wisconsin area who is board-certified in Anesthesiology and Pain Medicine. Dr. Hasan owns, operates and controls the Defendant Center. References hereafter to "Dr. Hasan" shall mean and include *both* of the named Defendants in this case.
- 4. Dr. Nasheen Hasan also owns individually a building at 7235 West Appleton Avenue in Milwaukee, at which the Defendant Center was located until early 2016, and at which a clinical laboratory operation has been operated entirely by Midwest Laboratory Sales & Consulting, LLC ("Midwest Lab"), since 2011.
- 5. This case concerns the submission by and on behalf of Dr. Hasan, since 2012 and continuing as of the filing of this Complaint, of thousands of legally and factually false claims for payment to the Medicare and Medicaid insurance systems for laboratory tests of urine samples received from patients purportedly diagnosed by Dr. Hasan with "chronic pain," and for whom Dr. Hasan had prescribed, or was expected to prescribe, oxycodone. All such claims falsely represented that the conduct of the Urine Drug Testing had been personally supervised by Dr. Hasan incident to her treatment of

the individual patients involved in her pain clinic, when in fact Dr. Hasan had no direct or indirect involvement in the actual supervision of, the conduct of, or any decision to order or authorize, any such specific test. All such claims in fact resulted from the Defendants' agreement to refer all of the urine samples gathered by the Defendants to the independently-operated Midwest Lab for the performance of all such urine drug tests, in exchange for which Midwest Lab agreed to allow Dr. Hasan to submit all claims to federal insurers in Dr. Hasan's name, and to collect from each claim substantially more in revenue than Dr. Hasan agreed to pay to the Midwest Lab for the actual conduct of each test, in violation of the statute identified below as the Anti-Kickback Act.

- 6. That remunerations-for-referrals agreement, as well as all resulting referrals of urine specimens, all resulting urine drug tests, and all claims by Dr. Hasan for payments resulting from all such urine drug tests, took place in Milwaukee, Wisconsin, and thus in the Milwaukee Division of the Eastern District of Wisconsin.
- 7. Also included in this case are factually and legally false claims by a separate independent laboratory (which is not a party to this action) for payments for separate "confirmation" urine drug tests, the medical necessity of which was never determined because of Dr. Hasan's professionally negligent and reckless disregard of her duty to provide the medical judgment of a physician, in compliance with the standard of medical care applicable to such professional judgments, prior to authorizing a further laboratory test of urine samples for the purpose of "quantitative confirmation" tests

following the conduct of initial "qualitative" urine drug tests of urine samples from Dr. Hasan's patients by Midwest Lab.

The False Claims Act

- 8. The False Claims Act (FCA) provides in pertinent part, through 31 U.S.C. § 3729(a)(1), that:
 - (a) Any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government; ... or (G) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

* * *

is liable to the United States Government for a civil penalty of not less than \$5,500 and not more than \$11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person....

9. For the purpose of that provision, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1)(A). For a Defendant to act "knowingly" with respect to a false claim and thus to be liable under the FCA, there is no requirement that the Defendant be proven to have acted with a specific intent. The conduct by the Defendants as described below,

which renders them jointly liable to the United States under the FCA, included conduct engaged in with deliberate ignorance and reckless disregard, in violation of the FCA and also in violation of the standard of professional care applicable to such practicing physicians in the State of Wisconsin.

Medicare, Medicaid, and the Anti-Kickback Act

- 10. The United States, through the U. S. Department of Health and Human Services ("HHS") and its component agency the Center for Medicare and Medicaid Services ("CMS"), administers the Medicare Part B insurance program, including the payment of lawful claims by clinical laboratories and physician clinics.
- 11. HHS also oversees, and State agencies administer, the Medicaid program of health insurance for persons determined not to be financially able to pay for private health insurance. In the State of Wisconsin, the Medicaid program is administered by the Wisconsin Department of Health Services. Medicaid is a federal/state partnership under which, in the case of Wisconsin, the United States through HHS pays for approximately sixty percent (60%) of the program's expenses, while the State of Wisconsin pays for the remaining percentage of approximately forty percent (40%). Approximately twenty percent (20%) of Wisconsin residents receive health insurance through the Medicaid program.
- 12. Physicians, their clinics, and other health care providers who participate in the Medicare program are required to enter into contracts (or "Medicare Enrollment").

Applications") with CMS, in a contract form known as a "CMS-855I" form.

- 13. Dr. Hasan entered and periodically renewed such a contract with Medicare. Her compliance with the terms of that contract with respect to any one treatment, procedure, or clinical test was a legal prerequisite to her ability lawfully to submit any claim for payment by Medicare for any such activity, and her certifications in that contract and each such renewal thereof were implicitly but inherently used as a part of, and renewed contemporaneously with, each of her claims to Medicare and Medicaid for reimbursement of any laboratory procedure or test.
- 14. Dr. Hasan on her own behalf as a physician, and also on behalf of the Defendant Clinic as its owner and operator, therefore executed an Enrollment Application and Agreement with CMS in which each of them represented that they "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with (Medicare) laws, regulations, and program instructions . . . expressly "including" the "Federal anti-kickback statute" among other federal health care laws. Each such Defendant therefore had actual knowledge, prior to any claim of the kind alleged to be legally false in this case, that its entitlement to be paid under any such program any amount for any claim was conditioned on that claim not being the result of and not arising from any activity undertaken in exchange for any inducement paid or offered in violation of the Anti-Kickback Act ("AKA"), codified at 42 U.S.C. § 1320a-7b(b), which provides as follows:

(B) Illegal remunerations

- (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
- (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined no more than \$25,000 or imprisoned for not more than five years, or both.

- (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to any person to induce such person –
- (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal Health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined no more than \$25,000 or imprisoned for not more than five years, or both.

15. The federal AKA arose out of congressional concern that financial inducements to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, and even harmful to a vulnerable patient population. To protect the integrity of the Medicare program from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment

of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to widen the scope of what constitutes an illegal remuneration under the AKA. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242 subparts b and c; 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Anti-abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

- 16. One of the purposes of the AKA is to ensure that health care providers compete for business based on the quality and efficiency of care provided to patients.

 When important health care decisions are influenced by improper inducements, competition among health care providers is diminished. Consequently, patient care suffers, as an incentive is created for health care providers to distinguish themselves based on the financial inducements they offer, rather than on the quality and efficiency of services they provide.
- 17. This broad scope and the substantial penalties reflect the significance of the prohibition against kickbacks as a critical tool in the fight against health care fraud. *See* H. Rep. 95-393, 95th Cong., 1st Sess. at 44, *reprinted in* 1977 U.S.C.A.N. 3039, 3047. Indeed, as part of the comprehensive health care reform legislation enacted in 2010, Congress amended the AKA to emphasize that "a claim that includes items or services resulting from a violation of this section, constitutes a false or fraudulent claim for purposes of [the False Claims Act]." Patient Protection and Affordable Care Act of 2010

(PPACA), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. § 1320a-7b(g)).

FACTUAL ALLEGATIONS

18. This case concerns claims to Medicaid and Medicare for payments arising out of laboratory tests of urine samples obtained by Dr. Hasan at the Defendants' very-high-volume "pain clinic," from thousands of patients purportedly diagnosed by Dr. Hasan as suffering from "chronic pain." The laboratory tests primarily involved here were "qualitative" tests of urine samples, meaning that they were designed to test the presence (or absence) of drugs or metabolites, also known as "analytes," in a patient's biological system.

(A) Defendants' AKA Violations

- 19. On or about November 2, 2011, the Defendants entered, and continue to operate as described below, a "Management Services Agreement" with Midwest Lab (hereafter, "MSA Agreement"), under which the Defendants agreed and promised to refer *exclusively* to Midwest Lab all of the urine specimens gathered from the Defendants' pain clinic patients for the performance of all "qualitative" laboratory tests conducted as to such specimens.
- 20. The Defendants knew at all relevant times that Midwest Lab was owned, controlled, supervised and operated entirely independently of the Defendants.
 - 21. In their MSA Agreement the Defendants specifically agreed that Midwest

Lab alone "shall have the exclusive right to provide the Services" of a laboratory as to all such urine samples referred by the Defendants' clinical operation, and agreed that Midwest Lab, rather than either of the Defendants, would be solely responsible to "manage, supervise, staff and coordinate the day-to-day clinical operations taking place at the Diagnostic Lab" run by Midwest Lab. Midwest Lab, and not the Defendants, was allocated exclusive responsibility to "hire and appoint the on-site lab manager" to be employed exclusively by Midwest Lab, to "provide the technical personnel" necessary to conduct the laboratory tests, and "for hiring and firing the Support Personnel, and determining the salaries" for laboratory personnel, for "the selection of all laboratory equipment and related supplies" required for the laboratory work, and to "maintain and keep current all written policies and procedures for the Diagnostic Lab" established to receive the referral by the Defendants of all of the Defendants' patients' urine samples.

- 22. David Petsch, the lab technician who performed all urine drug tests and conducted all of the reviews and analyses of all results of all qualitative tests performed on urine samples of Dr. Hasan's patients, was employed, paid, and supervised exclusively by Midwest Lab, and not by either Defendant (or any employee or agent of either Defendant).
- 23. The only responsibility or obligation agreed to by Dr. Hasan in the Defendants' MSA Agreement with Midwest Lab was (1) to refer all of the Defendants' laboratory work and urine specimens to Midwest Lab during the period of the Agreement, and (2) to provide physical space (with utilities therefor and housekeeping thereof) for

Midwest Lab to operate the laboratory. Dr. Hasan in fact only assigned to Midwest Lab one former "patient room" inside Dr. Hasan's clinic to serve as a "laboratory."

- 24. No part of the MSA Agreement between Dr. Hasan and Midwest Lab required Midwest Lab to compensate either Defendant for the market value of the laboratory space owned by the Defendants, and no such compensation was ever paid.
- 25. Instead, the sole consideration promised and paid by Midwest Lab to the Defendants for the exclusive referral arrangement represented by the MSA Agreement was an agreement to shift to the Defendants the exclusive opportunity to bill Medicare, Medicaid and other insurers (in Dr. Hasan's name and provider number) for all laboratory tests performed by and under the exclusive control of Midwest Lab (as if the Defendants had performed and were entitled to be paid for the tests, which they knew they were not), and a contractual right to keep at least one-half (50%) of the gross proceeds of such federal and other insurance claims (with Midwest Lab to be paid the remaining half of such proceeds, for having performed and supervised all of the lab work for which the payments were intended). The same remuneration-for-referrals agreement provided that the Defendants' per-test compensation to Midwest Lab would "vary with actual patient volume" during the life of the arrangement.
- 26. In knowingly and willfully agreeing to, entering, operating, and receiving the financial benefits of, the MSA Agreement, the Defendants each knowingly and willfully received substantial revenues from its billings to federal health care programs for resulting

urinalyses and other laboratory tests, all in exchange for the Defendants' referrals of all such urine samples to Midwest Lab for testing, and thereby violated the AKA as set forth above, as a result of which each and every claim for each urinalysis or other laboratory test presented by or on behalf of the Defendants to Medicare or Medicaid since the entry of the MSA has been a legally false claim within the meaning of the FCA.

27. The Defendants' compliance with the Anti-Kickback Act was a legally necessary and material prerequisite to the Defendants' entitlement to be paid on any such claim. If the persons receiving and paying such claims for laboratory work on behalf of those federal insurance programs had known the truth that those claims resulted from a violation of the Anti-Kickback Act, those claims would not have been paid.

(B) Defendants' Failure to Supervise the Conduct of, or to Determine the Medical Necessity of, Urine Drug Tests Performed by Midwest Lab

- 28. As a legal prerequisite to either of the Defendants' entitlement to be paid by Medicaid or Medicare for laboratory tests including urine drug tests, each test must have been performed "incident to" the physician's personal treatment of the patient, the physician must have remained actively involved in the direct supervision of the conduct of the testing procedure, and the test must have been an actual expense to the physician or physician's clinic. The Defendants satisfied none of these criteria with respect to the urine drug tests rendered by Midwest Lab for Dr. Hasan's "chronic pain" patients.
 - 29. As a further legal prerequisite to either Defendants' entitlement to be

paid by Medicaid or Medicare for any laboratory test including urine drug tests, a physician must have determined that each such test was reasonable and necessary for the medical treatment or diagnosis of the individual patient based on her or his particular medical condition. 42 U.S.C. § 1395y(a)(1)(A). The need for each such test for each such patient must have been individually assessed and documented in the patient's medical chart, as a legally material and necessary prerequisite to the validity of any payment for any such test. 42 C.F.R. §§ 410.32(a) & (d)(2).

- 30. In negligently and recklessly failing to determine the medical necessity of each such test as to each such patient, Dr. Hassan signed, as the purported medical authorization of all urine drug tests of all urine samples referred by the Defendants to Midwest Lab since early 2012, a single, one-time "Lab Requisition" form authorizing lab referrals generally, at a time when that form had no patient name and no other patient-specific information on it.
- 31. Without any medical analysis or decision having been made or documented by Dr. Hasan about the medical necessity of each or any test for any particular patient, Dr. Hasan instructed her clinical staff negligently, recklessly and fraudulently to reproduce that single pre-signed "Requisition" form and use it as the "order" purporting to document the "medical necessity" of all such tests, as well as the medical necessity of all "confirmation" urine tests later performed by a further independent lab (as described below).

- 32. Neither Dr. Hasan, nor any other physician or licensed health care professional representing either Defendant, performed, in compliance with the applicable standard of medical care or otherwise, any activity to conduct, supervise the conduct of, review the performance of, interpret the results of, or otherwise scrutinize the conduct of, any of the urine drug tests performed by Midwest Lab.
- 33. All qualitative, "presumptive" urine drug tests performed by Midwest Lab pursuant to the remuneration-for-referral exchange contemplated by the MSA Agreement have been performed as on-site Urine Drug Tests, utilizing a "Biolis24i" chemistry analyzer and an immunoassay methodology.
- 34. Each such qualitative urine drug test involved in this case was designed to detect the presence or absence of the following: oxycodone, Benzodiazepine, cocaine, methoadone, marijuana, Buprenorphine, heroin, opiates and alcohol.
- 35. When such tests are properly conducted and supervised, a personally-supervising physician is allowed properly to bill Medicaid or Medicare utilizing a billing procedure code known (through 2015) as code "G0431," intended to compensate physician-supervised "qualitative" drug screens involving "multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay)." Each such bill for each such "encounter" or drug test, if properly performed and billed, entitled a physician to receive a payment in the amount of \$102.99 from Medicaid or Medicare. (During 2016, the same procedure or test was re-coded using the symbol "GO479," and for 2017 the same

procedure or test has in turn been described with a code of "80307").

- 36. The Defendants, through a third-party billing entity named Fi-Med (located in Brookfield, Wisconsin), submitted payment claims to the Medicare and Medicaid systems since May of 2012, in the name and provider number of Dr. Hasan (using the NPI Provider Number of 1003800285 in each such case), for substantially all of the Urine Drug Tests performed exclusively by Midwest Lab under the MSA Agreement described above, representing in the course of each such payment claim that the test had been performed or supervised by Dr. Hasan (as "incident to" her medical practice and her individual care of her patients).
- 37. Such a representation that a test had been performed "incident to" the medical practice of a physician, thus entitling the physician to be compensated for the laboratory work and result, required that the physician actively, directly, and personally supervise the conduct of the tests.
- 38. Neither Dr. Hasan, nor any employee of the Defendant Center, in fact actively supervised or was personally involved in the conduct or monitoring of any of the urine drug tests which were billed on behalf of the Defendants to federal insurers. That fact rendered all such payment claims by the Defendants factually and legally false when presented, as the Defendants knew.
- 39. Between the beginning of Midwest Lab's operation as the exclusive referee of Dr. Hasan's qualitative laboratory testing work in 2012, until early 2016, the Midwest

Lab operation was located in the same building, owned by Dr. Hasan, as the Defendants' Clinic, at 7235 West Appleton Avenue in Milwaukee, Wisconsin. During early 2016, Dr. Hasan moved the entire clinic operation to an entirely different part of the Milwaukee area, at 6200 West Center Street, Milwaukee, which was located approximately 1.9 miles away from the West Appelton Avenue location. The Midwest Lab operation, however, remained at the West Appleton Avenue location, where it operates today. That re-location of that clinic 1.9 miles away from the laboratory changed nothing about the level of supervision or oversight by Dr. Hasan of the Urine Drug Tests referred to Midwest by the Defendants. There had been no such supervision or oversight before that re-location, and there was none after the re-location of the clinic.

- 40. All payment claims submitted by or on behalf of Dr. Hasan submitted to Medicare and Medicaid utilizing the procedure code "G0431" (and the revised codes for the same procedure or test utilized in 2016 and 2017) inherently represented that Dr. Hasan had actively supervised the conduct of a "qualitative" (and "presumptive") urine drug test, involving "multiple drug classes by high complexity tests method."
- 41. All such representations inherent in all such payments claims were factually false, rendering the payment claims legally false as well. In fact, neither of the Defendants performed, or supervised, or were involved in any medically meaningful way in, any such test or work.
 - 42. A further and separate legal prerequisite to the Defendants' entitlement to be

paid for any such Urine Drug Test procedure was compliance by the relevant laboratory with the certifications and credentials required by the the Clinical Laboratory Improvement Amendments ("CLIA") administered by the U. S. Food and Drug Administration ("FDA").

- 43. A material part of the CLIA certificate obtained and utilized by Midwest Lab was the representation to CMS (directly by Midwest and indirectly by the Defendants) that Dr. Hasan was acting (and would act) as the "Laboratory Director" of all of the laboratory work performed by Midwest Lab.
- 44. Because Dr. Hasan was not actively or personally supervising that laboratory work, she did not serve as a Laboratory Director, and knew at the time of the presentation of each claim to Medicaid or Medicare for compensation for each such test that she had not performed that function.
- 45. The validity of Midwest Lab's CLIA certificate was implicitly represented and used by the Defendants upon the presentation of each such payment claim as a material prerequisite to the validity of each such claim. Midwest Lab's CLIA certificate was in fact false and invalid.
- 46. If the falsity and invalidity of that CLIA certificate had been known by payment personnel at the time of each such payment claim, no such claim would have been paid on behalf of Medicaid or Medicare. For this additional reason, therefore, all such payments claims were legally and factually false when made in the name of (and

under the provider number of) Dr. Hasan.

- 47. Each such payment claim by the Defendants to Medicare and Medicaid resulted in a payment to the Defendants of \$102.99 throughout 2012, \$99.95 throughout 2013, \$99.20 throughout 2014, \$98.96 throughout 2015, \$79.25 throughout 2016, and \$79.81 thus far in 2017. (The code name and number assigned to the same testing procedure changed as of 2016 from the earlier "G0431" to "G0479," and then in 2017 to "80307").
- 48. The Defendants are known to have billed as many as forty-five (45) or more such Urine Drug Test panels for a single day, and submitted to Medicare and Medicaid over 500 tests monthly since the beginning of 2012.

(C) Defendants' Failure to Supervise Decisions by Non-Physician Employees of Midwest Lab about When to Re-Refer Urine Samples for Follow-Up, Quantitative "Confirmation" Drug Tests

- 49. Some, but not all, of the urine samples from Dr. Hasan's patients which have been subjected by Midwest Lab to urine drug tests have thereafter been the subject of rereferrals by Midwest Lab to a separate and independent laboratory for the purpose of conducting follow-up "quantitative" urine drug tests to "confirm" the precise quantities of drugs found in Midwest Lab's "qualitative" urine drug tests. Such second-level tests are often referred to as "confirmatory" or "confirmation" tests.
- 50. The Defendants until 2014 utilized for the purpose of such "confirmatory" quantitative testing Millennium Laboratories, Inc. ("Millennium"), and since 2014 have

caused Midwest Labs to make referrals exclusively to Aegis Sciences Corporation ("Aegis") for the conduct of all such confirmatory tests.

- As a legal prerequisite for any health care provider to be compensated by Medicaid or Medicare for any such quantitative "confirmatory" lab test, a physician must initially have determined the medical necessity of the confirmatory test, through an individual assessment of the patient's medical needs and the proper documentation in the patient's files of that need and that assessment. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 410.32(a) and 410.32(d)(2).
- 52. Neither of the Defendants in this case performed any such individual assessment or diagnosis of the medical necessity of confirmatory Urine Drug Tests for any of their patients, and knew that no other licensed physician was doing so, and as a result negligently, recklessly and knowingly caused, first Millenium and then (beginning in 2014) Aegis, to submit to Medicaid and Medicare legally and factually false claims for payment for the confirmatory tests involving urine samples of the Defendants' patients.
- 53. Dr. Hasan's reckless disregard for the medical necessity of all such quantitative confirmatory tests, in violation of the medical standard of care required under Wisconsin law for the lawful conduct of such activities by a physician, has caused many factually and legally false claims to be paid by Medicaid and Medicare for such confirmation tests.

(D) Defendants' Disregard of the Results of (and the Absence of the Medical Necessity of)

<u>Urine Drug Tests by Midwest Labs</u> of Specimens from New Clinic Patients.

- 54. Even after Dr. Hasan began to refer all of the Defendants' urine samples for qualitative tests by Midwest Lab in early 2012, the Defendants nevertheless continued to conduct, through their own clinic staff and as to each urine sample received from all of the clinic's new, first-time "chronic pain" patients, in-house "CLIA-waived" urine drug tests through an in-clinic "test cup" procedure. Because results from those tests were made available to Dr. Hasan by the clinic staff within a matter of minutes after the urine samples were gathered, and before the Clinic's new patients left the clinic building, Dr. Hasan routinely used the results of those in-house "test cup" urine drug tests as the clinical basis for routinely prescribing oxycodone to such new patients before the end of their first clinic visit.
- 55. Results of CLIA-eligible urine drug tests by Midwest Lab, however, were not available to Dr. Hasan until days after the first such clinic visit by the same new patients. The Defendants referred urine samples of such new patients to Midwest Lab, not as part of any medical diagnostic or treatment process, but solely in order to share in the monetary proceeds of the claims resulting from those tests. By the dates on which the Midwest test results were received by Dr. Hasan, the Defendants' own in-house "test cup" tests had already been used by Dr. Hasan as the diagnostic basis for writing an oxycodone prescription during such patients' first clinic visit.
 - 56. Dr. Hasan knew that results from the Midwest Lab tests would not be used

for diagnostic or treatment purposes for those patients, and therefore knew that the qualitative urine drug tests referred to Midwest Lab for those patients were medically unnecessary. Pursuant to and because of the kickback arrangement between the Defendants and Midwest Lab, the referrals were made anyway.

- 57. All claims arising from all such referrals to Midwest of urine samples of all such new patients of Dr. Hasan violated the prerequisite for payment entitlement represented by 42 CFR § 410.32(a), which requires that "clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary."
- 58. All of the conduct by each of the Defendants alleged above, and which results in the Defendants' liability as set forth below, was caused by Dr. Hasan's negligent and reckless failure to follow or abide by the standard of care applicable to supervision of and billing practices regarding laboratory tests, as well as knowing conduct (as that term is defined in the FCA).

COUNT I

Claim By and on Behalf of the United States under the FCA Against Defendant Clinic and Defendant Hasan (Causing False Claims to be Presented)

- 59. Plaintiff re-alleges and incorporates by reference paragraphs 5 through 58 as though fully set forth herein.
- 60. This is a claim under the False Claims Act, 31 U.S.C. §§ 3729-33, as amended, against both Defendants herein, meaning the Defendant Clinic (as defined

above) and Dr. Hasan individually, as to their joint and several liability for the same conduct by each.

- 61. The Plaintiff/Relator, Jon Fering, has standing to maintain this claim by virtue of 31 U.S.C. §3730(b).
- 62. By virtue of the acts described herein, the Defendants each knowingly made, and caused to be made and presented, false or fraudulent claims for payment to be presented to officials of the Wisconsin Department of Health Services, and Medicare payment officials, and thus to officials of the United States Government (and/or asserting claims for funds of the United States), in violation of 31 U.S.C. § 3729(a)(1)(A).
- 63. By virtue of the false claims knowingly caused to be presented by each of the two Defendants, the United States has suffered actual damages and is entitled to recover three times the amount which it paid in response to all such false claims (and therefore the amount by which it is damaged), plus civil money penalties of not less than \$5,500 and not more than \$11,000 for each of the false claims caused to be presented, and other monetary relief as appropriate.

COUNT II

Claim By and on Behalf of the United States under the FCA Against Defendants Clinic and Hason (Causing False Record or Statements to be Used to Get, and/or Which were Material to, False Claims Paid)

- 64. Plaintiff realleges and incorporates by reference paragraphs 5 through 58 as though fully set forth herein.
- 65. This is a claim on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729-33, as amended, against both Defendants herein, as to their joint and several liability to the United States.
- 66. The Plaintiff/Relator, Jon Fering, has standing to maintain this claim by virtue of 31 U.S.C. §3730(b).
- 67. By virtue of the acts described above and the Defendants' use of, or activities causing to be used, false records and statements (including, but not limited to as described above, representations that laboratory tests were conducted "incident to" Dr. Hasan's treatment of patients) to get false and fraudulent claims paid and approved by Medicare and Medicaid payment officials, and otherwise the Defendants' acts causing false records and statements to be used to obtain such payments, which were material to false or fraudulent claims, the Defendants caused to be made or used false records or statements to get false or fraudulent claims paid or approved by an agency of the United States Government, and also caused to be made or used false records or statements which were material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

68. By virtue of, and as a result of, the false records and statements used to get false claims paid by the Government, the United States has suffered actual damages and is entitled to recover three times the amount by which it is damaged (here meaning three times the amount paid by Medicare and Medicaid for laboratory tests for which payments were made), plus civil money penalties of not less than \$5,500 and not more than \$11,000 for each of the false claims presented or caused to be presented, and other monetary relief as appropriate.

COUNT III

Claim By and on Behalf of the United States under the FCA Against the Defendant Clinic and Defendant Hasan (Conspiracy to Submit False Claims)

- 69. This is a claim under the False Claims Act, 31 U.S.C. §§ 3729-33, as amended, against both Defendants herein.
- 70. Plaintiff realleges and incorporates by reference paragraphs 5 through 58 as though fully set forth herein.
- 71. By reason of the foregoing each of the Defendants agreed and conspired with Midwest Lab, to defraud the government in order to get false or fraudulent claims paid by Medicare and Medicaid, in violation of 31 U.S.C. § 3729(a)(1)(C) as amended in 2009. In furtherance of the conspiracy, and through each of the particular activities described above, each of the two Defendants acted overtly to affect the objects of the conspiracy alleged herein through their conduct itemized above.

72. By virtue of the false claims presented or caused to be presented by the Defendants pursuant to this conspiracy, the United States has suffered actual damages and is entitled to recover from each Defendant, jointly and severally, three times the amount by which it is damaged, plus civil money penalties of not less than \$5,500 and not more than \$11,000 for each of the false claims presented or caused to be presented, and other monetary relief as appropriate.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in favor of the United States:

- 1. On Counts I III, under the False Claims Act, against the Defendant Clinic and Defendant Hasan, jointly and severally, for treble (i.e., three times) the amount of the United States' actual damages (including investigative costs), plus civil penalties as are allowable by law for each and every false claim or record and for all costs of this civil action.
- 2. For all costs of this civil action, including all investigative and expert expenses incurred herein; and
- 3. For such other and further relief as the Court deems just and equitable.
 WHEREFORE, Relator Jon Ferring demands and prays that judgment be entered in his favor:
 - 1. On Counts I III, under the False Claims Act, for a percentage of all civil

penalties and damages obtained from either of the Defendants pursuant to 31 U.S.C. § 3730, reasonable attorney's fees, investigative costs, expert witness fess incurred, and all costs incurred in pursuing these claims against the Defendants; and

2. Such other relief as the Court deems just and proper.

This the 20th day of December, 2017.

Respectfully submitted,

JONATHAN B. FERING, Relator

By his Attorneys,

PIGOTT LAW FIRM, P.A.

By:

J. Brad Pigott

J. Brad Pigott, Mississippi Bar No. 4350

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Mississippi Bar No. 4350

Admitted to U. S. District Court, Eastern Dist. of Wisconsin, on November 6, 2017

Certificate of Service

I hereby certify that I have submitted the foregoing Complaint to the Clerk of this Court, by placing the foregoing in the United States Mails this day, for a non-electronic filing "under seal" pursuant to 31 U.S.C. § 3730(b)(2).

This the 20th day of December, 2017.

J. Brad Pigott, Esquire